EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-31

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	Epidemiologic Support for IRIS

Contractor	Specify Section and paragraph of Contract SOW
ICF Incorporated, L.L.C.	A.1,2; B.1,2,3,4,5; C.1; D; and G.1,2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

[ ] Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) [ ]

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Amanda Persad (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9781 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-31

TITLE: Epidemiologic Support for IRIS

Principal Section & Paragraph of SOW: A.1,2; B.1,2,3,4,5; C.1; D; and G.1,2

PERIOD OF PERFORMANCE: November 1, 2014 – October 31, 2015

I. PURPOSE

This work assignment is a follow-on to work performed in the Base Period under Work Assignment 0-31. The purpose of this work assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter, EPA) National Center for Environmental Assessment (NCEA), within the Office of Research and Development (ORD). The specific purpose is to provide expert epidemiologic support for the development of Integrated Risk Information System (IRIS) scientific materials, including both qualitative and quantitative analyses and syntheses of human data and exposure information as identified in the contract performance work statement, Sections A(1 and 2); B(1,2,3,4 and 5); C (1); D and G (1 and 2) .

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on health effects that may result from exposure to environmental contaminants. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. By combining IRIS toxicity values with specific exposure information, government and other entities use IRIS to help characterize public health risks of chemical substances and thereby support risk management decisions designed to protect public health.

The IRIS Program is currently developing the 2015 IRIS agenda. The draft list of chemicals anticipated to appear on the agenda is provided in Appendix A. Assessments for some of these chemicals are in progress and others will be initiated in the coming fiscal years. In response to the evolving needs of EPA's Program Offices and Regions and IRIS Program resources, additional chemicals may be added to the agenda, and some chemicals may be dropped. Scheduling of chemical assessments will depend on a number of factors, including regulatory/ programmatic priorities, availability of staff and other resources, and potential public health impact of an assessment. Therefore, the IRIS Program will need to preserve flexibility in determining which assessments, whether the chemical is listed in Appendix A at this time or not, will require assistance during the period of performance of this Performance Work Statement (PWS).

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Requirements Specific to this Work Assignment

Under this WA, an episode of work (aka "request") will be initiated by written Technical Direction (TD). Each request will clarify deadlines for delivering drafts and final work products. An initiating TD will identify the data and the specific Tasks (as outlined below) to be performed.

The Contractor shall prepare documents in the format specified in the current IRIS standard operating procedures and templates (to be provided by EPA). Recent examples of final and draft assessments for other chemicals may also serve as models. Documents shall be technically edited for format and grammar before being delivered to the EPA Work Assignment Manager (WAM).

The Contractor will be given an account in HERO (Health and Environmental Research Online), with access to scientific literature. Copyright law of the U.S. (Title 17 U.S. Code) governs the making of reproductions of copyrighted material. Section 107 of the copyright act instructs that, "the fair use of a copyrighted work for purposes such as ... research, is not an infringement of copyright." The Contractor is liable for any infringement of copyright. To set up the HERO account, the Contractor shall send an email to hero@epa.gov - and include the following information: Names, addresses, phone numbers, emails of all contractors needing HERO accounts, project name, start date and end date. The contractors will receive their HERO account information, with user documentation, within 3 business days.

HERO shall be used for performing literature searches. The literature search shall include, at a minimum, the following databases: PubMed, Web of Science, ToxNet; but may include others, as appropriate. The results from the literature search shall be submitted to HERO, as described in the user documentation. EPA will provide the PDFs through the HERO interface.

The Contractor shall use HERO (Health and Environmental Research Online) for reference citation and bibliographic generation, as described in the user documentation.

The Contactor will develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code, scripts, and software instructions used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The contactor will provide access to this internal documentation upon request by the EPA WAM or EPA Project Officer.

The Quality Assurance Project Plan (QAPP) developed under WA 0-31 during the Base Period will be used for this work assignment. The scope of work is not expected to change for this WA. A kick-off conference call has been completed under WA 0-31 and thus is not required for this WA.

Task 1: Develop a Work Plan

The Contractor shall prepare a written work plan proposing a technical approach to the work assignment. The work plan shall outline how the work shall be performed and provide a list of deliverables and interim deliverables with the schedule for completion. In addition, the budget and staffing plan and a brief description of the qualifications of the key technical staff shall be included. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

Deliverable Schedule: Work plan due in accordance with the contract.

Task 2: Quality Assurance Project Plan (QAPP) [completed in Base Period]

Task 3. Kick-off Conference Call [completed in Base Period]

Task 4: Manage, Identify and Recruit Expert Epidemiologists

The Contractor shall identify, recruit and manage expert epidemiologists ("experts") to develop sections of IRIS Toxicological Reviews and/or related materials. The Contractor shall be responsible for ensuring timely communication is passed between the EPA work assignment manager (WAM) and the experts so that technical clarification can be offered and interaction between EPA and the experts can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

EPA seeks to identify and recruit experts to develop several document sections/types for several different chemical assessments. These sections are discussed further in Task 5 within this WA, and they include:

1) Evaluation of exposure methods in epidemiological studies;

2) Study methods evaluations;

3) Evidence tables of specific health effects;

4) Graphical displays of evidence of specific health effects;

5) Other epidemiologic support (quantitative analysis, expert opinion, white papers, etc.).

EPA will provide guidance for the development of evidence tables and templates of the evidence and summary tables. The chemical assessments and related documents that will require assistance under this PWS will be clarified through technical direction.

The EPA assumes primary authorship in the writing process for all materials and contributing experts are listed in the final documents as appropriate. EPA will approve each of the experts performing work within two days of notification of a potential candidate.

Subtasks

1) **Identify and Recruit Expert Epidemiologists**

The Contractor shall identify and contact experts with a knowledge base that is aligned with the descriptions in each written TD. Each TD will specify the minimum/desired qualifications of the experts for that chemical assessment. The expertise needed will be specific to the broad field of epidemiology. Approximately 6-10 experts will be needed. Potential experts shall be asked to submit a bio-sketch to ensure they meet the minimum/desired qualifications, and EPA will notify the contractor of its concurrence with the selection.

2) **Manage Expert Epidemiologists**

The Contractor shall manage the recruited experts and ensure timely communication occurs between EPA and the experts. This shall involve setting up conference calls with the experts and EPA staff. In addition, the Contractor shall ensure that the written sections, comments and draft reviews are progressing on schedule and are delivered by the deadlines noted in this WA.

Deliverable Schedule: The schedule and specific expertise requested will be clarified within a TD.

Task 5. Complete Subtasks as Directed by EPA

The specific subtasks under this PWS, identified in Task 4, are described below. Specific clarification will be provided by the EPA WAM through Technical Direction. Technical Direction will be submitted individually for each chemical assessment or project, and the subtasks to be completed will be project-specific (i.e., not all of the subtasks will be completed for each project). EPA estimates that up to 6 work products related to one or more of the 5 primary tasks described below will be required over the period of performance of this PWS.

For some tasks (in particular subtasks 2 and 3 below), the Contractor may be asked to provide their work product using a database format. The database, and any necessary training or guidance on how to populate the database, will be provided to the Contractor by EPA.

1) Evaluation of exposure methods in epidemiological studies. The Contractor shall provide and manage experts to provide guidance and clarification regarding interpretation of exposure measures in epidemiological studies. This will include conducting a review of the reliability and validity of methods used in selected primary source studies, focusing on issues of nondifferential and differential misclassification. A tabular or draft synthesis of conclusions regarding different types of exposure measurement methods may be requested.

2) Study methods evaluation. The Contractor shall provide and manage experts to abstract relevant details pertaining to methods and other details of individual studies to allow for evaluation consistent with the systematic review process. The purpose of this task is to evaluate studies with respect to potential methodological considerations that could affect the interpretation of or confidence in the results by applying a series of specific questions, and documenting study evaluation in tables.

Study methods evaluations should be independent of considerations regarding the direction or magnitude of study results. Study methods evaluations will be performed at an early stage of assessment development, i.e., after identifying the relevant sources of primary data but before developing evidence tables and characterizing hazard associated with chemical exposure. EPA will provide templates or database for the Contractor to use in abstracting study information. The specific details as to what should be abstracted will be determined through consultation with the EPA WAM.

3) Evidence tables. The Contractor shall provide and manage experts to prepare evidence tables that summarize results from epidemiologic studies, consistent with the draft *Handbook for IRIS Assessment Development* and *Elements of an Evidence Table* (Appendix B). The Contractor shall also conduct quality assurance (QA) checks of evidence tables developed by the experts and/or provided by EPA that shall include the following: comparison of table entries to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m^3), confirming reported exposure ranges and effect measures, and inserting and verifying HERO links. The quality assurance checks should be performed by an expert that was not involved in the initial development of the table. EPA will provide the most current evidence table template or database for the

Contractor to complete the task.

4) Graphical displays. The Contractor shall provide and manage experts to prepare graphical displays of results from epidemiologic studies. Approaches used for categorical exposure data (e.g., forest plots) and approaches used for quantitative data (e.g., representing magnitude of exposure or exposure contrast in relation to magnitude of effect) may be requested; the Contractor will provide expertise to develop or modify graphical displays ass needed. The Contractor shall also conduct quality assurance (QA) checks of the data used to generate graphical displays that shall include the following: comparison of data to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m^3), and inserting and verifying HERO links. The quality assurance checks should be performed by an expert that was not involved in the initial development of the graphical display.

5) Other epidemiologic support. The Contractor shall provide and manage experts to address other issues that may arise within the context of the review of epidemiologic studies. These issues may pertain to ascertainment of specific outcomes in epidemiology studies, assessment of potential for confounding (e.g., through knowledge of co-exposures in specific workplaces or communities), and other questions regarding bias. This may also include quantitative modeling of epidemiologic data.

Deliverable Schedule: In general, work products shall be delivered in the following formats: tables for subtasks 2, and 3 and text for all remaining subtasks. The deliverable schedule will vary depending on the subtask(s) and chemical, and will depend on the amount and complexity of the information to be evaluated/summarized. The schedule will be clarified within a TD.

Task 6. Revision of Task 5 Deliverables

EPA will submit comments on the Task 5 deliverables. The Contractor shall provide and manage expert epidemiologic expertise to revise those deliverables based on EPA comments. The use of "redline" versions (track changes) of the document will be employed throughout the process. Tasks issued under this WA will be completed when all EPA comments have been considered and addressed, and may require multiple rounds of revision.

Deliverable Schedule: The deliverable schedule will vary depending on the subtask(s) and chemical. Unless otherwise specified in the TD, the Contractor will incorporate EPA comments within 7 days of receipt. The schedule will be clarified within the TD.

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be further clarified using written Technical Direction.

Task	**Schedule** (*all days are elapsed calendar days unless otherwise stated)
1. Develop a Work Plan	In accordance with contract

2. Quality Assurance Project Plan	completed
3. Kick-off Conference Call	completed
4. Manage, Identify and Recruit Expert Epidemiologists	To be clarified in written technical direction.
5. Complete Subtasks as Directed by EPA	To be clarified in written technical direction.
6. Revision of Task 5 Deliverables	To be clarified in written technical direction.

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Work Assignment Manager (WAM)
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Appendix A. Draft IRIS Agenda

Potential Chemicals List	CAS No.
*To be updated as needed	
acetaldehyde	75-07-0
acrylonitrile	107-13-1
ammonia	7664-41-7
arsenic, inorganic	7440-38-2
benzo(a)pyrene	50-32-8
n-butanol	71-36-3
tert-butanol	75-65-0
chlorobenzene	108-90-7
chromium VI	18540-29-9
1,4-dichlorobenzene (1,4-DCB)	106-46-7
diisopropyl ether (DIPE)	108-20-3
dinitrotoluene, technical grade	25321-14-6
ethylbenzene	100-41-4
ethyl tertiary butyl ether (ETBE)	637-92-3
ethylene oxide (inhalation, cancer)	75-21-8
formaldehyde	50-00-0
hexabromocyclododecane (HBCD)	3194-55-6, 25637-99-5
hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)	121-82-4
isopropanol	67-63-0
Libby amphibole asbestos	1332-21-4
manganese	7439-96-5
mercury, elemental	7439-97-6
methylmercury	22967-92-6
methyl tert-butyl ether (MTBE)	1634-04-4
naphthalene	91-20-3
perfluorooctanoic acid (PFOA)	335-67-1
perfluorooctanesulfonic acid (PFOS)	2795-39-3
phthalates	
butyl benzyl phthalate (BBP)	85-68-7
di-n-butyl phthalate (DBP)	84-74-2
diethyl phthalate (DEP)	84-66-2
di(2-ethylhexyl) phthalate (DEHP)	117-81-7
diisobutyl phthalate (DIBP)	84-69-5
diisododecyl phthalate (DIDP)	40989-56-8
diisononyl phthalate (DINP)	68515-48-0 and 28553-12-0
dipentyl phthalate (DPP)	131-18-0
polychlorinated biphenyls (PCBs) (noncancer)	various
polycyclic aromatic hydrocarbon (PAH) mixtures	various
tert-amyl methyl ether (TAME)	994-05-8
tert-amyl ethyl ether (TAEE)	919-94-8
trimethylbenzenes (1,2,3-,1,2,4-, and 1,3,5-isomers)	526-73-8, 95-63-6, 108-67-8
uranium (natural)	7440-61-1
vanadium, elemental and compounds	various
vanadium pentoxide	1314-62-1

Appendix B. Elements of an Evidence Table (for IRIS Assessments)

Evidence tables are an integral part of IRIS assessments. The first iteration of evidence tables is presented in Stage 1 of the IRIS process (Draft Development) as part of the "Preliminary Package" of public materials. Further iterations or versions of evidence tables are included at later stages of the IRIS process, and may vary depending upon the chemical database and needs of the specific assessment. General elements common to all evidence tables are described below; other elements (including those pertaining to study quality evaluation) may be added to the evidence tables and will vary in content and format to allow for the compilation of the most suitable approach for the respective body of information. These specific elements will be determined by the assessment team with consideration from the scoping and problem formulation process and members from the appropriate workgroup.

I. General elements:

All evidence tables should include the following:

- **Author, year and location of study**: reported in as much detail as possible – country/region, state, city, specific factories, etc.

Hayes et al. (1979) (United States)

- **Study description:** Present study design type, sample size, description of study participants and controls or reference group
    - Study design type: type of study with additional information as follows:
        - Cohort – length of follow up, % lost to follow up
        - Case-control – information on matching if performed
    - Sample size: the number of individuals or study units (e.g., couples, mother-child pairs) in various groups (may include: participation rate and data used in this derivation such as the number of participants recruited, number meeting selection criteria, number in final analysis/analyses, etc.)
    - Study population: This description should include:
        - Any relevant information on how the study population was selected (e.g., factory employment records), including any restrictions or inclusion/exclusions criteria (e.g., only workers with >1 year of job tenure)
        - Information on important demographic characteristics such as distribution of sex, age, and other outcome-specific factors (e.g., for pregnancy outcomes, may want to include parity; for lung cancer, may want to include smoking status)

Case-control study, 56 couples from assisted reproduction center, n=56 control couples (parents), mean age 39 years in both groups.

- **Exposure assessment:** Present how exposure was assessed (e.g., job exposure matrix, air sampling, etc). Also provide some measure of exposure levels (e.g., the mean and range of urinary concentrations of the chemical) for the study population, and/or for each group (e.g., the mean and range among the low and high exposed, or among cases and controls) if available.

- **Outcome assessment**: Present how was the outcome measured/evaluated (e.g., medical record, self-report, physician examination) and the degree that all cases were ascertained.

- **Analysis:** Present statistical methods (including any adjustment variables considered or used in the final analysis), and how results were evaluated. This should include details on how confounding was addressed as well as a description of how statistical significance/precision was evaluated (e.g., use of confidence intervals and/or significance tests).

Proportionate mortality (cancer) ratios, using the U.S. general population to generate expected mortality, adjusted for age, time period of death

- **Results:** Present overall or stratified results as available and appropriate, including any corresponding confidence intervals and/or p-values. If no quantitative results are available, a statement on the results as reported by the author will be provided, making clear that this is the authors' report and not EPA's judgment of results.

Authors note a marked increase in the prevalence of respiratory irritation among exposed workers.

II. Other considerations for generation of evidence tables (not exhaustive):

- **Table Format**: Modifications may be made to the table format depending on the specific database and needs of the assessment. For example, evidence tables may have 2 or 3 columns with the additional column designated for 'Exposure.'
- **Reporting information**: If information is not available, state that it is not reported (e.g. "Outcome: cardiovascular disease (ICD codes not reported)" or "Follow-up time not reported"]
- **Process/Interim Drafts**: It is suggested that the contractor provide an interim draft early in the development process (with about 5 study entries) for review by the epidemiology workgroup. This will allow for early feedback to the contractor prior to the completion of the evidence tables. Further feedback and discussion between the contractor and the epidemiology workgroup is expected throughout the development and evolution of the evidence tables.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-31

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	EPI IRIS Support
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A.1,2; B.1,2,3,4,5; C.1; D; and G.1,2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$55,603.00	430
Total:	$55,603.00	430

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/21/2014	$55,603.00	430
Cumulative Approved:	$55,603.00	430

Work Assignment Manager Name: Amanda Persad (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9781 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-31

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

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1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2016	$55,543.00	430
This Action:	$20,177.00	158
Total:	$75,720.00	588

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 09/17/2015	$20,177.00	158
Cumulative Approved:	$75,720.00	588

Work Assignment Manager Name: Amanda Persad (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9781 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

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Work Assignment

Work Assignment Number: 1-33

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Addressing Cumulative Risks
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues and Documents

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 12/16/2014 To 10/31/2015

Comments:
Science Technical Support for Analysis of Opportunities for Assessing and Addressing Cumulative Risks and Impacts by EPA Programs and Regional Offices

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

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Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Lawrence Martin (Signature) (Date)	Branch/Mail Code:	
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	FAX Number: 703-347-8696	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
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	Phone Number: 513-487-2852	
	FAX Number: 513-487-2107	

PERFORMANCE WORK STATEMENT
CONTRACT EP-C-14-001
WA 1-33

TITLE: Science Technical Support for Analysis of Opportunities for Assessing and Addressing Cumulative Risks and Impacts by EPA Programs and Regional Offices

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Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD of PERFORMANCE: CO approval through October 31, 2015

I. Purpose

This work assignment is a follow-on to work performed in the Base Period under Work Assignment # 0-33. The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) and Office of Science Advisor (OSA), Office of Research and Development (ORD), in the completion of technical analyses and papers on cumulative risk and cumulative impacts.

II. Background

Multiple aspects of the environment in which we live, learn, work, and play impact our health. Addressing multiple exposures to chemical and nonchemical stressors and cumulative risks and impacts in environmental decisions has long been a challenge for EPA and a concern of communities and environmental justice organizations. EPA's National Center for Environmental Research (NCER) is funding extramural research to develop methods and strategies for assessing the combined effects of chemical, physical and biological stressors while factoring in population vulnerabilities see http://www.epa.gov/ncer/cra/ . EPA's RAF is currently developing Agency guidelines on cumulative risk assessment, building upon existing methods for chemical mixtures risk assessment routinely employed by EPA programs and regions. EPA's CRA Guidelines will advance the science further, introducing additional quantitative and qualitative analytical strategies for examining combinations of multiple chemical, physical and biological stressors and understanding how to factor in population vulnerabilities, including socio-economic stressors. NCER and RAF Cumulative Risk Technical Panel recently collaborated on a successful 1 ½ year CRA Webinar Series that focused on methods for assessing cumulative risk and decision frameworks. Although there is strong public interest for EPA to not only conduct cumulative risk assessments and use the results in decision making, institutional and policy barriers at EPA may prevent the full incorporation and use of cumulative assessment in environmental decision-making by EPA. Therefore, ORD/NCER and the RAF seek technical and analytical services to address technical issues as follow-up to the CRA webinar series.

III. Statement of Work

A. Objective: Characterization of cumulative risk assessment (CRA) implementation by EPA program offices and regional offices.

The purposes of this work assignment are to obtain services to support: 1) the development and preparation of manuscript(s) addressing how EPA program and regional offices use CRA, 2) a characterization of the decisions

that are being informed by CRA, 3) identification of what statutory authority or rule the EPA program and regional offices are relying on for the CRA, and 4) technical editing of manuscripts addressing CRA.

B. Specific Requirements

Task 1: Analysis of Cumulative Risk Assessment use by EPA Program and Regional Offices

While there may be statutory authority for using cumulative risk assessment or analysis in decision making, each EPA program and regional office may develop policies and guidance regarding cumulative risk to suit their specific needs. The Contractor will complete an analysis of how cumulative risk assessment is currently used by EPA program and regional offices. The Contractor will draw upon information provided by EPA, a narrowly targeted literature review, as necessary, and interviews with approximately 20-30 EPA staff to be identified by the WAM. The Contract shall conduct the analysis to answer the following questions:

1. What EPA programs use CRA, and for what precise programmatic purpose?
2. What decisions are being informed by CRA for the purposes identified in #1, above?
3. What statutory authority or rule is associated with the use of CRA in #1, above, and what language in that statutory authority or rule are the EPA program and regional offices relying on for incorporation of CRA information into their decision making?

The Contractor will provide an outline for EPA review and comment, a draft monograph for review, a final draft for review, and a final approved manuscript. Final coordination of the manuscript shall follow editorial requirements under Task 3. The Contractor shall communicate regularly with the EPA COR (and technical advisor/s) to ensure suitable detail, focus and rationales.

An illustrative process for discovery might proceed as follows: A listing of EPA programs using CRA are identified from the literature or through the COR/WAM. A preliminary hypothesis about how CRA is addressed in research Qs #1-3 is developed for each program. Program contacts are identified and initial email connection addressed to determine if they are the right person to interview, or to ID correct person. Interviews are conducted by phone asserting hypotheses to interviewees (assumed not to exceed 45 minutes in length). Corroboration with additional detail, or correction to hypothesis is gained from interviewee/s. It is appropriate to email the summary of the interview to the interviewee for their corroboration, but the interviewee's signed approval is not necessary. Calls may not be recorded, but the Contractor may take notes, dependent on the Contractor's need and with the concurrence of the interviewee. Information on each interviewee should be appended to the report: Name, Office/Div./Branch, phone #, date of interview. In instances where conference calls are arranged with multiple participants, a list of all participants on the call should be included. A draft manuscript is sought for task #1 by Dec. 10, 2015.

Task 2: Scientific/Technical Editorial Services

The Contractor, as directed by the COR/WAM through written technical direction, shall develop technical manuscripts based on work conducted under Tasks 1. Additionally, other manuscripts or annotated outlines addressing scientific and technical dimensions of CRA may be delivered with technical direction for revision, editing and research. Such other manuscripts or annotated outlines will not exceed 300 pages in text exclusive of front matter and references, and technical direction for revisions, editing and research will not exceed 500 hours. The contractor shall provide both science/technical editorial services for the final copy of manuscripts generated. The range of editorial services shall include a review of each paper for meaning, formatting, and assuring that papers meet prescribed style requirements, spelling and grammar checks, researching references for accuracy, formatting bibliography, checking text for clarity, and formatting of graphics such as charts, symbols, and equations. The contractor shall discuss recommended edits for each paper with the authors,

following a consultation with the WAM, and prior to incorporating edits.

After science/technical editing, the contractor shall send a copy of each paper and a summary report of all significant amendments in response to comments, or changes effected through the science/technical editing process or otherwise to the WAM. The WAM and other EPA staff identified by the WAM will review the final manuscripts over a 21 day period. At the end of the EPA review, the WAM will send the manuscripts and any additional comments to the contractor. Upon receipt of the comments, the contractor shall consult with the authors on significant comments. The contractor shall edit the manuscripts according to the Technical WAM's comments. The contractor may sub-contract expertise necessary for specialized review and content editing and revisions.

The contractor shall finalize all manuscripts and submit camera ready copies of the manuscripts to the WAM in both pdf and MS word formats after incorporating the final comments from the WAM. The contractor shall also provide hard copies of each manuscript

IV. Schedule of Deliverables

1. The contractor shall send EPA all reports in accordance with the terms of the basic contract

2. The contractor shall submit a draft manuscript for task #1 by February 5, 2015.

3. Outputs from data analysis and indicator preparation may include charts, graphics, MS Excel files and descriptive text.

4. Formatted manuscripts – due one week after draft manuscripts provided to contractor.

5. Formatted EPA reports – due two weeks after draft report provided to contractor

6. Revised manuscripts/reports – due two weeks upon receipt of comments from WAM.

VI. Other Requirements

Periodic meetings between the EPA and contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WAM's discretion, these meetings may occur via teleconference or video conferences. The Contractor shall document these meetings and submit copies of this correspondence to the EPA WAM.

The EPA WAM may identify one or more EPA technical representatives for this work assignment. Interaction between the contractor and any EPA technical representative(s) designated by the PO is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. These interactions do not result in direction to the contractor.

All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or COR/WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

VIII. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA COR/WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA Contact Information

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

X. Work Assignment Manager (WAM)

Lawrence Martin
Science Coordinator
Risk Assessment Forum
U.S. EPA Office of Science Advisor
1200 Pennsylvania Avenue, N.W. (8105-R)
Washington, DC 20460
voice - 202.564.6497

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-33

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	Cumulative Risks and Impacts

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A. Assessment Issues and Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/16/2014 To 10/31/2015

Comments:
Science Technical Support for Analysis of Opportunities for Assessing and Addressing Cumulative Risks and Impacts by EPA Programs and Regional Offices

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$60,791.00	428
Total:	$60,791.00	428

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 01/14/2015	$60,791.00	428
Cumulative Approved:	$60,791.00	428

Work Assignment Manager Name: Lawrence Martin (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-6497 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-35

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Workshop
	Base Option Period Number 1	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW: A5. Assessment Issues and Documents ¿ Integrated S

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:
Workshop to Discuss Policy-Relevant Science to Inform EPA¿s Integrated Plan for the Review of the PM NAAQS

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Jennifer Richmond-Bryant (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-4518	
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 703-347-8523	
	FAX Number: 703-347-8696	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2852	
	FAX Number: 513-487-2107	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-35

TITLE: Workshop to Discuss Policy-Relevant Science to Inform EPA's Integrated Plan for the Review of the PM NAAQS

Principal Section & Paragraph of SOW: **A5. Assessment Issues and Documents – Integrated Science Assessments**

PERIOD OF PERFORMANCE: November 1, 2014 – October 31, 2015

I. PURPOSE

This work assignment is a follow-on to work performed in the Base Period under Work Assignment #0-35. The purpose of the work assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of providing administrative and logistical support for a 3-day workshop, planned for February 10-12, 2015. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND

Sections 108 and 109 of the Clean Air Act require periodic review and, if appropriate, revisions of the national ambient air quality standards (NAAQS) and the air quality criteria on which they are based. EPA will initiate a review of the primary and secondary NAAQS for the effects of particulate matter (PM) in the summer of 2014. As part of this review, EPA will first develop a draft integrated plan that will outline the schedule, process, and key policy-relevant issues that will generally be used to frame the science assessment, risk/exposure assessment, and policy assessment documents. These documents will provide the foundation to inform Agency decision-makers throughout the review of the NAAQS for PM.

To facilitate the development of this draft integrated plan, EPA plans to hold a workshop on or around February 10-12, 2015 to receive input from internal and external PM experts. Workshop participants shall be asked to discuss current and emerging science that may inform the key policy-relevant issues. The workshop discussions will be considered as the Agency develops the draft integrated plan to incorporate the most current, policy relevant science into the NAAQS technical support documents briefly described above.

III. STATEMENT OF WORK

A. Objective

The overall objective of this work assignment (WA) is to provide administrative and logistical support for the workshop described above. The workshop will be 3 days in length. The goal of the workshop is to ensure that this review focuses on the key policy-relevant issues and considers the most meaningful new science to inform our understanding of these issues. As stated above, speakers/panelists will present a variety of perspectives and facilitate an open dialogue on policy-relevant issues with discussions focused on health effects associated with PM exposure. The workshop discussions will provide important input as EPA considers the appropriate design and scope of the major elements of the PM review that will inform the Agency's policy assessment under the NAAQS process: as integrated plan highlighting the key policy-relevant issues; an integrated science assessment; and a risk and/or exposure assessment. Each session panel shall consist of several experts (EPA or

non-EPA) from a range of disciplines including epidemiology, toxicology, clinical sciences, dosimetry, exposure assessment, and atmospheric chemistry, with additional expertise on welfare effects, specifically visibility. The workshop shall have an expected attendance of approximately 250 participants, both in-person and through a webinar, including non-EPA experts, and shall be held at the U.S. EPA RTP campus. Conference rooms have been reserved on the US EPA campus in RTP for February 10-12, 2015. If an alternative date becomes necessary and needs to be rescheduled, EPA will submit to the contractor recommended alternative date (s) for the workshop. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks)

1. The contractor shall maintain communication with the EPA COR through weekly phone calls or email updates.

2. The contractor shall develop a candidate list of non-federal experts with broad based knowledge and expertise in the areas that inform health effects of PM, including atmospheric chemistry, exposure assessment, epidemiology, toxicology, clinical sciences, and dosimetry; and welfare effects, including expertise on visibility and climate effects; along with expertise in risk/exposure assessment with the goal of recruiting up to 2 of these experts to participate in the workshop. All experts should have an understanding of or experience with the NAAQS process. Potential invitees shall be asked to submit a bio-sketch to WA-COR for assessing their qualifications and to ensure they are sufficiently qualified in the proposed area of expertise (evidenced by education, experience, publications, etc.).

3. Once experts have been approved, the contractor shall formally invite each to the meeting.

4. The contractor shall arrange transportation, lodging, and logistical support for approximately 22 invited non-federal participants, as required. This will also include arranging the appropriate compensation (e.g., honoraria) for the time and effort of the non-federal experts.

5. The contractor shall provide assistance (including onsite assistance) to EPA prior to, during and after, the workshop. This may include the following:

    a. Prepare and make available electronic and paper copies of meeting materials including registration lists and other registration materials (preliminary and final agendas will be provided by EPA.) Prepare and make available hard copies of meeting materials for workshop attendees and nametags/name tents for panelists and invitees prior to the meeting. Coordinate facilities for presentation of the material (power point presentations). The Contractor shall provide draft materials to the COR for review and technical direction approximately one week prior to the deliverable due date.

    b. Collect information on panelist bio-sketches and AV needs.

    c. Set up a website for online registration and also on the spot registration site for invited as well as other EPA and non-EPA attendees.

    d. Set up and run two informational webinars in advance of the meeting for the invited participants to receive information on the workshop and have an opportunity to ask questions about their participation. The webinars will be offered at two separate times to accommodate panelists' schedules.

e. Set up the webinar that will coincide with each day of the meeting.

f. Compile and maintain mailing list and final attendance list of all attendees, both EPA and non-EPA.

g. Supply full-time on-site registration desk staff (2 people).

h. Provide on-site staff throughout the workshop to manage the webinar.

h. Provide on-site staff throughout the length of the workshop to coordinate with facility staff during planning, set-up, implementation and closeout of the event and to assist workshop participants, as appropriate.

i. Update attendee list at the end of the workshop (remove no-shows, add walk-ins).

j. Provide a complete table of travel expenses for the approximately 22 non-federal participants recruited under Task 1 or WA 0-35. The contractor shall itemize travel expenses for each participant by flight, hotel, non-hotel per diem, and other costs.

V. SCHEDULE OF DELIVERABLES

Deliverables	Due Dates
1.List of candidates submitted to COR for approval	November 7, 2014
2.Invite up to 2 experts for workshop participation	November 10, 2014
3.Submit electronic copies of registration lists,registration materials, and an agenda.	January 20, 2015
4.Submit updated list of registered attendees, electronic version of presentation materials, any materials submitted by presenters prior to or following the meeting, and an itemized table listing travel expenses for all non-federal participants recruited under Task 1 or WA 0-35.	1 week following workshop

VI. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or COR.

VII. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA COR at the initiation of the work assignment, and shall provide a weekly update to the COR by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VIII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Contracting Officer Representative (COR)
Jen Richmond-Bryant, PhD
919-541-4518
richmond-bryant.jennifer@epa.gov

Alternate COR
Steve Dutton, PhD
919-541-5035
dutton.steven@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-35

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Workshop
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A5. Assessment Issues and Documents & Integrated S

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$75,783.00	310
Total:	$75,783.00	310

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/21/2014	$75,783.00	310
Cumulative Approved:	$75,783.00	310

Work Assignment Manager Name: Jennifer Richmond-Bryant (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-4518 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-37

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Exposure-Related Information
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: D - Analysis, Document and Issue Paper Preparation

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/11/2014 To 10/31/2015

Comments:
Collection, Evaluation, and Archival of Exposure-Related Information for Consumer Products

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Kristin Isaacs (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2785 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-37

TITLE: Collection, Evaluation, and Archival of Exposure-Related Information for Consumer Products

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Specify Section & Paragraph SOW: D - Analysis, Document and Issue Paper Preparation

PERIOD of PERFORMANCE: CO approval through 10/31/2015.

Purpose: This work assignment (WA) is a follow-on to work performed in the Base Period under WA # 0-37. The purpose of this WA is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency). This WA is consistent with the purpose and scope of Contract EP-C-14-001.

Background

EPA has been developing novel approaches and tools for evaluating, screening and classifying chemicals for the Chemical Safety for Sustainability (CSS) Program based on the potential for biologically-relevant human exposures, for the purpose of informing toxicity testing and prioritization for risk assessment. Program Offices and other Stakeholders need the ability to readily use a flexible and integrated source to-dose-to-effects model with more realistic exposure modules for evaluating, screening and ranking risks from chemical exposures of different population and age groups.

NERL has developed an efficient and more generalizable high-throughput version of the Stochastic Exposure and Dose Simulations (SHEDS) modeling tool ("SHEDS-HT"). SHEDS-HT is being designed to fill critical gaps in data and numerical algorithms in order to comprehensively characterize key human exposure pathways within a multi-tier and efficient modeling framework. As part of a collaboration with NCCT's ExpoCast project, SHEDS results will be evaluated and incorporated into calibrated consensus exposure predictions within the Systematic Empirical Evaluation of Models (SEEM) framework.

The SHEDS-HT model is being parameterized for a large number of commercial chemicals present in consumer products, articles, foods, and drinking water. However, this parameterization effort requires the identification, collation, and documentation of many disparate sources of data related to consumer product use, composition, and purchasing.

EPA has also recently developed repository information related to chemical use, the Chemical and Product Categories (CPCat) Database, contained within NCCT's Aggregated Computational Toxicology Resource (ACToR). This database - which contains a variety of information related to the categorization of chemicals by functional, industrial, or other uses – is a high-value resource for developing and refining high-throughput exposure tools.

The focus of this project will be to collate and archive relevant exposure-related consumer product information from a variety of sources (in a documented, structured form) to support the development and expansion of SHEDS-HT, ExpoCast, and CPCat.

The WACOR is authorized to provide technical direction in accordance with the contract. This PWS instructs the Contractor to perform the tasks are described below.

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

The Contractor shall submit a work plan outlining the entire technical approach and cost estimates, quality assurance procedures to be conducted, the schedule for the WA completion. Following review by the WACOR, should any changes be required, a final revised work plan shall be submitted by the Contractor **within 7 days of receipt of WACOR comments and recommendations**.

Task 2. Collect, Document, and Archive Quantitative Exposure-Related Data from Danish Consumer Product Surveys

The Danish Environmental Protection Agency has conducted a large number of surveys of chemicals found in consumer products, incorporating information from manufacturer reporting, targeted manufacturer surveys, and laboratory assessments. Detailed reports are available for over 100 such surveys at http://eng.mst.dk/topics/chemicals/consumers-consumer-products/danish-surveys-on-consumer-products/. These reports contain potentially useful quantitative information related to product compositions (e.g. mass percent of chemical in products) or default/measured exposure factors (e.g. transfer of chemical to skin). The Contractor will collect from these reports such composition and exposure factor data and store it in a structured form provided by the WACOR. Other non-quantitative chemical use information (e.g. functional use of chemicals within products, simple presence/absence of chemical within product categories) should also be documented in a format consistent with CPCat.

The WACOR will provide guidelines for data or database formats (e.g. MySQL), for compatibility with EPA's ACToR and/or CPCat databases, **within 2 weeks of EPA issuing the WA to the contractor**.
The Contractor will deliver to the WACOR all numerical data, chemical categorizations, and appropriate metadata (original source location, etc.) extracted from the Danish reports in the designated database format. The Contractor will also prepare a brief technical memo describing the data collection, QA procedures, and any assumptions made. The Contractor will deliver the database and technical memo to the WACOR **on or before December 31, 2014**.

Task 3. Collect, Document, and Archive Consumer Product Ingredients from MSDS Sources
EPA has previously collected consumer product ingredient information from a retailer-provided Material Safety Data Sheet (MSDS) repository (Goldsmith et al., *Food and Chemical Toxicology* 65:269-279, 2014). Methods were developed for 1) programmatically extracting the chemical ingredients, CAS numbers, and product names from MSDS sheets in to a MySQL database using custom scripts and 2) manually curating composition information for each product ingredient using a web-enabled interface.

The WACOR will provide a list of additional existing manufacturer, retailer, or industry group MSDS data sources to the Contractor. It is anticipated that these sources will comprise on the order of 1000-5000 MSDSs (products). The Contractor will use the methods of Goldsmith et al. (or similar methods) to extract product composition information from the MSDS sheets. The contractor will also assign to each identified product one or more consumer product categories consistent with CPCat or SHEDS-HT. In addition, data sources for information on chemical use (functional or otherwise) may be identified as well for automated data extraction. The WACOR will provide scripting tools, curation interface, and/or database format guidelines **within 2 weeks of EPA issuing the WA to the contractor**.

The Contractor will deliver to the WACOR all CASRNs, numerical composition data, chemical categorizations, chemical uses and/or appropriate metadata (original source location, etc.) extracted from the MSDSs or other sources in the designated database format. The Contractor will also prepare a brief technical memo describing the data collection, QA procedures, and any assumptions made. The Contractor will deliver the database and technical memo to the WACOR **on or before January 31, 2015.**

Task 4. Locate UPC Information for Consumer Products

EPA has recently obtained a proprietary database of consumer product purchases made within the U.S. This database contains product-level information, indexed by UPC code. To facilitate the merging of this database with consumer product chemical ingredients, the Contractor will obtain UPC codes (when available) for the approximately ~9000 consumer products contained in the EPA's Consumer Product Chemical Profile Database (CPCPdb). The UPC codes will be obtained via searches of publically available UPC databases or from retailer sites (via Google searches of product names).
The list of consumer products contained in the CPCPdb will be provided to the Contractor by the WACOR **within 2 weeks of EPA issuing the WA to the contractor**.

The Contractor will deliver to the WACOR a matched list of consumer products and UPC codes in Excel spreadsheet form **on or before March 31, 2015.**

QA/QC Requirements for WA:

The WA-COR will develop an approved quality assurance project plan (QAPP) that will be provided to the Contractor prior to the Contractor beginning Task 2. The QAPP will be developed based on Chapter 3 for projects using existing data within the EPA Guidance for QAPPs (EPA QA/G-5) that can be found here, http://www.epa.gov/quality/qs-docs/g5-final.pdf. The QAPP will identify responsibilities of both EPA and the Contractor, and lay out quality objectives and criteria. Note that the Contractor may begin work on Task 1 (Work Plan development) prior to delivery of the QAPP. The Contractor will adhere to the QAPP when completing Tasks 2-4.

Deliverables:

A meeting shall be arranged and conducted by the Contractor to discuss the initiation of the tasks with the WACOR. Subsequently, phone conferences or meetings shall be conducted by the Contractor on a bi-weekly basis to discuss with the WACOR the progress and any issues associated with the tasks. The Contractor shall adhere to the following schedule:

Task	Deliverable	Delivery Schedule
1	Conference Call	3 days after receipt of WA
2	Database of information from Danish consumer product reports and accompanying Technical Memo	December 31, 2014
3	Database of information from MSDS data sources and accompanying Technical Memo	January 31, 2014
4	Matched list of CPCPdb consumer products and UPC codes	March 31, 2015

Reporting Requirements:

The Contractor shall provide monthly progress reports in accordance with the terms of the contract. In addition, the Contractor shall deliver to the WACOR any draft and final reports in electronic format that is readable by windows-based word-processing (Microsoft Word 2003), graphics (Microsoft PowerPoint 2003), spreadsheet (Excel 2003), and database (MySQL) programs.

Work Assignment Contracting Officer's Representative (WACOR):
WACOR: Kristin Isaacs
Phone: (919) 541-2785

Alternate WACOR Name: Peter Egeghy
Phone: (919) 541- 4103

U.S. Environmental Protection Agency
Office: ORS/NERL
Division (Mail Code): HEASD (E205-02)
109 TW Alexander Drive
Research Triangle Park, NC 27711
Phone: (919) 541-2785

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-37

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Exposure Related Information
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: D - Analysis, Document and Issue Paper Preparation

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/11/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$77,543.00	983
Total:	$77,543.00	983

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 12/31/2014	$77,543.00	983
Cumulative Approved:	$77,543.00	983

Work Assignment Manager Name: Kristin Isaacs (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2785 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-38

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Androgen Disruption Pathway
	Base Option Period Number 1	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW: G. Literature Search

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Michael Loughran (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-6686 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
Contract Number: EP-C-14-001
Work Assignment Number 1-38

Title: Androgen Disruption Pathway Systematic Literature Search

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PWS Section & Paragraph: G. Literature Search

PERIOD OF PERFORMANCE: November 1, 2014 thru October 31, 2015

I. PURPOSE:

The purpose of this work assignment is to apply the systematic review process in the characterization of chemical literature on the androgen pathway, specifically focused on non-monotonicity in the dose-response relationship. Compare the literature results identified via the systematic review process to the results provided in the 2013 EPA SOS document to determine whether selection of a particular literature review process impacts the overall findings. Subsequent to this review, it would important to be able to compare the dose(s) at which NMDR is found to occur with doses currently used in regulatory decisions to begin the process of determining whether the current risk assessment paradigm is sufficiently protective of human health and the environment.

II. BACKGROUND:

In 2013, EPA contracted with the National Academies of Science's Board of Environmental Studies and Toxicology to provide an expert peer review and request public comment on the draft state of the science paper. The purpose of the state-of-the-science paper is to help EPA policy makers determine if NMDRs capture adverse effects that are not detected using current chemical testing strategies and if there are adverse effects that current EPA testing misses.

The EPA workgroup reviewed various scientific studies and the results were detailed in the draft NMDR SOS paper submitted to NAS on June 18, 2013. While EPA is interested in all aspects of NMDR, the SOS paper focuses on endocrine disruptors – in particular estrogen, androgen and thyroid active chemicals.

On May 2, 2014, the National Academy of Sciences released its review of EPA's draft paper State of the Science on Non monotonic Dose Responses. Among the NAS comments and recommendations was a clear focus on the lack of consistency and transparency in terms of documentation of literature search methods, criteria for evaluating study quality and unclear data synthesis and weight of evidence methods. The NAS panel indicated that this inconsistency led to differences in methods used to identify studies for consideration; selection of study inclusion and exclusion criteria and their application; selection of criteria for evaluating study quality; choice of data presentation, weighting and analysis and summarization of the data. Recommendations to address this issue of inconsistency and lack of transparency focused on the development of an analytic plan and application of the systematic evidence review process.

III. STATEMENT OF WORK

Task 1: As an initial task, a Quality Assurance Project Plan (QAPP) needs to be developed for this specific project. QAPPs are project specific and are part of the project planning process. The QAPP should outline the QA/QC for this specific project and be developed consistent with the Agency document "Guidance for Quality Assurance Project Plans (EPA QA/G-5)" available at http://www.epa.gov/quality/qs-docs/g5-final.pdf. Chapter 3 focuses on projects that use existing data and will be particularly relevant to this work. The QAPP must be approved by EPA before implementation.

Task 2: Determine whether a different literature review strategies (Systematic Review Process) used to identify repeated dose studies for chemicals that disrupt the androgen pathway would produce a different outcome than that presented in the 2013 EPA State of the Science document. If so, what is the difference? The review should be conducted for the following chemicals and their structural analogs: vinclozolin, phthalates, semicarbazide, prochloraz, trenbolone and testosterone.

2a) As an initial step, conduct a preliminary review of the literature for the list of compounds provided above and determine what is the environmentally relevant dose/concentration in different media (e.g., food intake levels, ambient air, etc.). This will help to establish what is considered "low dose" for the chemicals, respectively.

2b) Apply Step 2 of the focused systematic review process (see Appendix I.) and document the rationale for all search terms, exclusion and inclusion criteria (see below for examples) and submit the overall analytical plan for EPA's review and approval before proceeding to next step of extracting the studies for evaluation.

2c) Compare this focused systematic literature search results with those compiled in the 2013 EPA State of the Science Review document for the chemicals listed and determine whether there is a difference in the number and types of studies that may drive a different conclusion than that described in the State of the Science document.

Task 3: Define the number of extant studies that explore perturbation of the androgen pathway that used a large number of dose groups to inform whether there are adverse effects in the lower dose region.

3a) Apply Step 3 of the systematic review process listed in Appendix I. Extract data on the number of dose or concentration groups (or exposure ranges from epi studies) into collection forms that distinguish human, animal (species) and in vitro studies, and populate this information into an easily searchable database or tabular spreadsheet.

3b) A comparison of the number of studies with ≤ 4 doses vs. those with ≥ 5 doses should be completed and details on dose spacing and the extent to which there is coverage in the lower dose region should be documented. Definition of low dose may be defined as doses that are approximately 1-2 orders of a magnitude around those doses most relevant to humans and the environment.

All extracted data and meta-data should be consistent with QA/QC procedures to ensure accuracy.

Task 4: Assessing for Study Quality and Risk of Bias (Apply Step 4 of the systematic review process).

4a) For those studies identified in Task 2, assess the study quality, including: 1) reporting quality, 2) internal and 3) external validity

4b) Assess the risk of bias (risk that will overestimate or underestimate the true effect) categorized as definitely low, probably low, probably high and definitely high risk of bias following pre-specified criteria detailed in the protocol.

4c) For those chemicals tested with ≥4 doses in repeated dosing studies, identify the current agency regulatory point of departure (if available) to determine the difference in values, if any.

4d) Compile a comparative table by chemical and study type, of the risk of bias score, the NOAEL/LOAEL with points of departure values from agency hazard assessment documents (e.g., IRIS values, MCL/MCLG, Pesticide Risk Assessments and other agency peer reviewed hazard assessments). If a regulatory value is not available, please note N/A on the table.

Examples of Some Inclusion and Exclusion Study Criteria

Inclusion Criteria 1: Minimum of 4 dose levels inclusive of a control group evaluated
Inclusion Criteria 2: Evidence of a statistically significant NMDR on any androgen endpoint (e.g., changes in accessory sex tissue weights, gonadal weight, gonadal somatic index and/or anogenital distance, levels of spermatogenesis, and testosterone)
Exclusion Criteria 3: Absence of observations at lower dose levels in the study that would have been used to determine the LOEL/LOAEL
Exclusion Criteria 4: Not reproducible - absence of other corroborating published reports on this chemical where effects were observed at low levels.
Exclusion Criteria 5: absence of other published reports for effects on other endpoints that would have been used to determine the LOEL/NOEL below the dose identified as an NMDR.
Inclusion Criteria 6: Absence of study quality concerns or statistical power issues that weakened confidence in the NMDR observation.

Task 5. Delivery of the Final Product

The Contractor shall deliver three (3) hard copies in addition to the electronic version (MS Office 2007 unless otherwise stipulated) of the edited document and comparative tables to the COR. All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents etc.)

IV. SCHEDULE AND DELIVERABLES

Product	Due Date
Task 1. Conference Call.	In accordance with contract
Task 2. QA Project Plan	In accordance with the contract
Task 3. Shall conduct systematic review process on select chemicals.	As specified in the Technical Direction.

Task 4. Shall extract requested data and meta-data into a spreadsheet or database.	As specified in the Technical Direction.
Task 5. Shall assess studies for quality and risk bias, and assemble a comparative table by chemical and study type.	As specified in the technical direction.
Task 6. Shall deliver three (3) hard copies and one (1) electronic version (MS Word 2007) of the draft document to the COR.	As specified in the technical direction.

V. MANAGEMENT CONTROLS

Periodic meetings between the EPA and the Contractor WA managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WA COR's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA WA COR.

The EPA WA COR may identify one or more EPA technical representatives for this WA. Interaction between the Contractor and any EPA technical representative(s) designated by the EPA WA COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this WA. The interaction will be technical communication via technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO COR and the EPA WA COR or alternate EPA WA COR are the only representatives of the CO authorized to provide technical direction.

Per the technical direction clause, the CO and PO will be provided with copies of all technical direction.

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

The Contractor shall provide technical support in collecting and entering data in spreadsheets, organizing information, and summarizing, evaluating and synthesizing literature related to the topics described above. These tasks require expertise in multiple disciplines such as epidemiology, toxicology, pharmacology, physiology, pathology, microbiology, public health, decision analysis, quantitative dose-response assessment, quantitative uncertainty analysis, human health economics, biostatistics, chemistry, and mathematical modeling,

including Benchmark Dose (BMD) modeling, physiologically-based pharmacokinetic (PBPK) modeling, and computational toxicology modeling.

The tasks also require expert personnel having the knowledge and ability to conduct a thorough search of the literature and to fully and critically evaluate study methodologies and results in the technical disciplines identified above. Analyses must be scientifically sound and sufficiently documented.

VIII. EPA CONTACT INFORMATION

Work Assignment COR:

Michael Loughran
Immediate Office of Assistant Administrator
U.S. EPA (8101-R)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone: (202) 564-6686
Fax: (202) 564-2070

Alternate WA COR:

Monica Rodia
Office of Science Policy
U.S. EPA
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone: (202) 564-8322
Fax: (202) 564-

Appendix 1: 7 Step Systematic Review Process:

Objective: The principles of systematic review can be successfully applied to environmental health questions to provide greater objectivity and transparency to the process of developing conclusions. It provides a framework to document and justify the decisions made.

1. Problem formulation and protocol development
    a. Objective of the evaluation clearly stated with key questions to be addressed
    b. Questions: populations, exposures, comparators, outcomes, timings and setting of interest
2. Search for and select studies for inclusion
    a. Dates of search, frequency of updates and any limits placed on the search
    b. All studies screened for relevance to key questions, development of inclusion and exclusion criteria checklist a priori
    c. Plans for review of the data and to reconcile differences between reviewers and documenting rationale for exclusions
3. Extract data from studies
    a. Separate data collection forms for human, animal and in vitro studies
    b. Data base that would be publically viewable
4. Assess the quality of risk of bias of individual studies
    a. Study quality includes: 1) reporting quality , 2) internal and 3) external validity
    b. Risk of bias (risk that will overestimate or underestimate the true effect) categorized as definitely low, probably low, probably high and definitely high risk of bias following pre-specified criteria detailed in the protocol
5. Rate the confidence in the body of evidence
    a. Grading of recommendations assessment, development and evaluation (GRADE): high confidence, very low confidence
    b. Factors that decrease confidence (risk of bias, unexplained inconsistency, indirectness, imprecision and publication bias)
    c. Factors that increase confidence (large magnitude of effect, dose response, residual confounding increases confidence and cross species/population/study consistency)
6. Translate the confidence ratings into level of evidence for health effect
    a. High level of evidence, moderate levels of evidence and low level of evidence and evidence of no health effect
7. Integrate the evidence to develop hazard identification conclusions
    a. Known to be hazard to humans, presumed, suspected, not classifiable, not identified to be hazard to humans
    b. Evidence streams for human studies and non-human animal studies which have remained separate through the previous steps are integrated along with other relevant data

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-38

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Androgen Disruption Pathway
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: G. Literature Search

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments: Androgen Disruption Pathway Systematic Literature Search- see new PWS for changes

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2015		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: Michael Loughran (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-6686 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
Contract Number: EP-C-14-001
Work Assignment Number 1-38

Title: Androgen Disruption Pathway Systematic Literature Search

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PWS Section & Paragraph: G. Literature Search

PERIOD OF PERFORMANCE: Award – October 31, 2015

I. PURPOSE:

The purpose of this work assignment is to apply the systematic review process in the characterization of chemical literature on the androgen pathway, specifically focused on non-monotonicity in the dose-response relationship. Compare the literature results identified via the systematic review process to the results provided in the 2013 EPA SOS document to determine whether selection of a particular literature review process impacts the overall findings. Subsequent to this review, it would important to be able to compare the dose(s) at which NMDR is found to occur with doses currently used in regulatory decisions to begin the process of determining whether the current risk assessment paradigm is sufficiently protective of human health and the environment.

II. BACKGROUND:

In 2013, EPA contracted with the National Academies of Science's Board of Environmental Studies and Toxicology to provide an expert peer review and request public comment on the draft state of the science paper. The purpose of the state-of-the-science paper is to help EPA policy makers determine if NMDRs capture adverse effects that are not detected using current chemical testing strategies and if there are adverse effects that current EPA testing misses.

The EPA workgroup reviewed various scientific studies and the results were detailed in the draft NMDR SOS paper submitted to NAS on June 18, 2013. While EPA is interested in all aspects of NMDR, the SOS paper focuses on endocrine disruptors – in particular estrogen, androgen and thyroid active chemicals.

On May 2, 2014, the National Academy of Sciences released its review of EPA's draft paper State of the Science on Non monotonic Dose Responses. Among the NAS comments and recommendations was a clear focus on the lack of consistency and transparency in terms of documentation of literature search methods, criteria for evaluating study quality and unclear data synthesis and weight of evidence methods. The NAS panel indicated that this inconsistency led to differences in methods used to identify studies for consideration; selection of study inclusion

and exclusion criteria and their application; selection of criteria for evaluating study quality; choice of data presentation, weighting and analysis and summarization of the data. Recommendations to address this issue of inconsistency and lack of transparency focused on the development of an analytic plan and application of the systematic evidence review process.

III. STATEMENT OF WORK

Task 1: As an initial task, a Quality Assurance Project Plan (QAPP) needs to be developed for this specific project. QAPPs are project specific and are part of the project planning process. The QAPP should outline the QA/QC for this specific project and be developed consistent with the Agency document "Guidance for Quality Assurance Project Plans (EPA QA/G-5)" available at http://www.epa.gov/quality/qs-docs/g5-final.pdf. Chapter 3 focuses on projects that use existing data and will be particularly relevant to this work. The QAPP must be approved by EPA before implementation.

The nature of this work requires that some important quality control checks will be developed as the project progresses and defined in a protocol. The QAPP would benefit from a simple flow diagram that indicates items like when EPA must be consulted and approve the protocol. The protocol is also a critical document for describing QA/QC procedures and should be added to the QAPP. This means the QAPP will be updated at least three times to include the approved version – before commencing Task 3a, Task 3b and Task 4.

See specific comments in the QAPP made using Adobe sticky notes. It's unclear if ICF recognizes that the QAPP is designed to be the blueprint for the work and so should be written specifically for this project and broadly distributed and understood by all team members.

1. To avoid redundancy in the proposed staffing, please provide a flow diagram of the task and personnel that would be part of the implementation.

Task 2: Determine whether a different literature review strategies (Systematic Review Process) used to identify repeated dose studies for chemicals that disrupt the androgen pathway would produce a different outcome than that presented in the 2013 EPA State of the Science document. If so, what is the difference? The review should be conducted for the following chemicals and their structural analogs: vinclozolin, phthalates, semicarbazide, prochloraz, trenbolone and testosterone.

2. The systematic review process shall be applied for the substances listed above, but should also include any known metabolites of concern for human exposures. These chemicals have been included in the EPA's State of the Science document and should serve as the reference list, along with the baseline for study inclusion. The initial search terms used in the SOS document has been transferred to ICF for initial consideration. This transaction should be mentioned in the draft work plan.

2a) As an initial step, conduct a preliminary review of the literature for the list of compounds provided above and determine what is the environmentally relevant dose/concentration in different media (e.g., food intake levels, ambient air, etc.). This will help to establish what is considered "low dose" for the chemicals, respectively.

2b) Apply Step 2 of the focused systematic review process (see Appendix I.) and document the rationale for all search terms, exclusion and inclusion criteria (see below for examples) and submit the overall analytical plan for EPA's review and approval before proceeding to next step of extracting the studies for evaluation.

2c) Compare this focused systematic literature search results with those compiled in the 2013 EPA State of the Science Review document for the chemicals listed and determine whether there is a difference in the number and types of studies that may drive a different conclusion than that described in the State of the Science document.

3. **Task 3: Define the number of extant studies that explore perturbation of the androgen pathway that used a large number of dose groups to inform whether there are adverse effects in the lower dose region.** Please provide the rationale behind the estimations for number of articles for literature search and screening (n=1000); characterization on relevance (n=200) and those identified as relevant and require extraction based on previous steps (n=60).

3a) Apply Step 3 of the systematic review process listed in Appendix I. Extract data on the number of dose or concentration groups (or exposure ranges from epi studies) into collection forms that distinguish human, animal (species) and in vitro studies, and populate this information into an easily searchable database or tabular spreadsheet.

3b) A comparison of the number of studies with $\leq$4 doses vs. those with $\geq$5 doses should be completed and details on dose spacing and the extent to which there is coverage in the lower dose region should be documented. Definition of low dose may be defined as doses that are approximately 1-2 orders of a magnitude around those doses most relevant to humans and the environment.

4. All extracted data and meta-data should be consistent with QA/QC procedures to ensure accuracy. Please provide clarification on the accessibility of any proposed software (e.g., DRAGON) and what limitations, if any, the decision to use the software tool might have in terms of how the extracted data may be shared.

Task 4: Assessing for Study Quality and Risk of Bias (Apply Step 4 of the systematic review process).

4a) For those studies identified in Task 2, assess the study quality, including: 1) reporting quality, 2) internal and 3) external validity

4b) Assess the risk of bias (risk that will overestimate or underestimate the true effect) categorized as definitely low, probably low, probably high and definitely high risk of bias following pre-specified criteria detailed in the protocol.

4c) For those chemicals tested with ≥4 doses in repeated dosing studies, identify the current agency regulatory point of departure (if available) to determine the difference in values, if any.

4d) Compile a comparative table by chemical and study type, of the risk of bias score, the NOAEL/LOAEL with points of departure values from agency hazard assessment documents (e.g., IRIS values, MCL/MCLG, Pesticide Risk Assessments and other agency peer reviewed hazard assessments). If a regulatory value is not available, please note N/A on the table.

Examples of Some Inclusion and Exclusion Study Criteria

Inclusion Criteria 1: Minimum of 4 dose levels inclusive of a control group evaluated
Inclusion Criteria 2: Evidence of a statistically significant NMDR on any androgen endpoint (e.g., changes in accessory sex tissue weights, gonadal weight, gonadal somatic index and/or anogenital distance, levels of spermatogenesis, and testosterone)
Exclusion Criteria 3: Absence of observations at lower dose levels in the study that would have been used to determine the LOEL/LOAEL
Exclusion Criteria 4: Not reproducible - absence of other corroborating published reports on this chemical where effects were observed at low levels.
Exclusion Criteria 5: absence of other published reports for effects on other endpoints that would have been used to determine the LOEL/NOEL below the dose identified as an NMDR.
Inclusion Criteria 6: Absence of study quality concerns or statistical power issues that weakened confidence in the NMDR observation.

Task 5. Delivery of the Final Product

The Contractor shall deliver three (3) hard copies in addition to the electronic version (MS Office 2007 unless otherwise stipulated) of the edited document and comparative tables to the COR. All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents etc.) Due to the delay in schedule, please update the Exhibit 1 Proposed Deliverables Schedule.

IV. SCHEDULE AND DELIVERABLES

Product	Due Date
Task 1. Conference Call.	In accordance with contract
Task 2. QA Project Plan	In accordance with the contract
Task 3. Shall conduct systematic review process on select chemicals.	As specified in the Technical Direction.
Task 4. Shall extract requested data and meta-data into a spreadsheet or database.	As specified in the Technical Direction.
Task 5. Shall assess studies for quality and risk bias, and assemble a comparative table by chemical and study type.	As specified in the technical direction.
Task 6. Shall deliver three (3) hard copies and one (1) electronic version (MS Word 2007) of the draft document to the COR.	As specified in the technical direction.

V. MANAGEMENT CONTROLS

Periodic meetings between the EPA and the Contractor WA managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WA COR's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA WA COR.

The EPA WA COR may identify one or more EPA technical representatives for this WA. Interaction between the Contractor and any EPA technical representative(s) designated by the EPA WA COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this WA. The interaction will be technical communication via technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO COR and the EPA WA COR or alternate EPA WA COR are the only representatives of the CO authorized to provide technical direction.

Per the technical direction clause, the CO and PO will be provided with copies of all technical direction.

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

The Contractor shall provide technical support in collecting and entering data in spreadsheets, organizing information, and summarizing, evaluating and synthesizing literature related to the topics described above. These tasks require expertise in multiple disciplines such as epidemiology, toxicology, pharmacology, physiology, pathology, microbiology, public health, decision analysis, quantitative dose-response assessment, quantitative uncertainty analysis, human health economics, biostatistics, chemistry, and mathematical modeling, including Benchmark Dose (BMD) modeling, physiologically-based pharmacokinetic (PBPK) modeling, and computational toxicology modeling.

The tasks also require expert personnel having the knowledge and ability to conduct a thorough search of the literature and to fully and critically evaluate study methodologies and results in the technical disciplines identified above. Analyses must be scientifically sound and sufficiently documented.

VIII. EPA CONTACT INFORMATION

Work Assignment COR:

Michael Loughran
Immediate Office of Assistant Administrator
U.S. EPA (8101-R)
1200 Pennsylvania Avenue, N.W.
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Fax: (202) 564-2070

Alternate WA COR:

Monica Rodia
Office of Science Policy
U.S. EPA
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone: (202) 564-8322
Fax: (202) 564-

Appendix 1: 7 Step Systematic Review Process:

Objective: The principles of systematic review can be successfully applied to environmental health questions to provide greater objectivity and transparency to the process of developing conclusions. It provides a framework to document and justify the decisions made.

1. Problem formulation and protocol development
    a. Objective of the evaluation clearly stated with key questions to be addressed
    b. Questions: populations, exposures, comparators, outcomes, timings and setting of interest
2. Search for and select studies for inclusion
    a. Dates of search, frequency of updates and any limits placed on the search
    b. All studies screened for relevance to key questions, development of inclusion and exclusion criteria checklist a priori
    c. Plans for review of the data and to reconcile differences between reviewers and documenting rationale for exclusions
3. Extract data from studies
    a. Separate data collection forms for human, animal and in vitro studies
    b. Data base that would be publically viewable

4. Assess the quality of risk of bias of individual studies
    a. Study quality includes: 1) reporting quality , 2) internal and 3) external validity
    b. Risk of bias (risk that will overestimate or underestimate the true effect) categorized as definitely low, probably low, probably high and definitely high risk of bias following pre-specified criteria detailed in the protocol
5. Rate the confidence in the body of evidence
    a. Grading of recommendations assessment, development and evaluation (GRADE): high confidence, very low confidence
    b. Factors that decrease confidence (risk of bias, unexplained inconsistency, indirectness, imprecision and publication bias)
    c. Factors that increase confidence (large magnitude of effect, dose response, residual confounding increases confidence and cross species/population/study consistency)
6. Translate the confidence ratings into level of evidence for health effect
    a. High level of evidence, moderate levels of evidence and low level of evidence and evidence of no health effect
7. Integrate the evidence to develop hazard identification conclusions
    a. Known to be hazard to humans, presumed, suspected, not classifiable, not identified to be hazard to humans
    b. Evidence streams for human studies and non-human animal studies which have remained separate through the previous steps are integrated along with other relevant data

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-38

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Androgen Disruption Pathway
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	G. Literature Search

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$62,823.00	628
Total:	$62,823.00	628

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 02/09/2015	$62,823.00	628
Cumulative Approved:	$62,823.00	628

Work Assignment Manager Name: Michael Loughran (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-6686 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-39

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Connectivity Report
	Base Option Period Number 1	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues & Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Laurie Alexander (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8630 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-39

TITLE: Technical Support for Production of Final Connectivity Report

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Principal Section & Paragraph of SOW: **A. Assessment Issues and Documents**

PERIOD of PERFORMANCE: November 1, 2014 thru October 31, 2015

I. PURPOSE

The purpose of this Performance Work Statement (PWS) is to provide services to the U.S. Environmental Protection Agency's (EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD) in creating the final report titled "*Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence (September 2013 External Review Draft)*" (Final Report, Final Connectivity Report), based on revisions to the second external review draft of the report (Draft Report, Draft Connectivity Report).

II. BACKGROUND AND SCOPE

EPA is revising the external review Draft Connectivity Report, which reviewed and synthesized the peer-reviewed literature on the connectivity or isolation of streams and wetlands to large water bodies such as rivers, lakes, estuaries, and oceans. This draft was used to inform draft guidance and draft proposed rulemaking activities by the U.S. EPA's Office of Water that were designed to clarify questions of jurisdiction under the Clean Water Act.

The purpose of the activities proposed in this PWS is to provide assistance to EPA in revising the Draft Report to produce the Final Report and provide assistance in creating a response to comments document that addresses the Science Advisory Board (SAB) review comments on the Draft Report.

III. TECHNICAL APPROACH

The Contractor shall provide technical support to NCEA within the level of effort (LOE) allotted under this PWS. EPA will document work on the tasks such that the sources of all information, assumptions, methods, and analyses are briefly but clearly identified and described. EPA will not duplicate any work performed by the Contractor under other work assignments or agreements, including (but not limited to) other current work assignments under this contract.

This PWS consists of the following tasks:

Task 1: Kick-off Call

The Contractor shall participate in a kick-off call with the EPA technical team to discuss tasks and deliverables in this PWS.

Task 2: Work Plan and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this PWS will be performed, including deliverables, a schedule, budget, and level of effort. As part of the Work Plan, the Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan and that shows assigned personnel by task.

Within the Work Plan, the Contractor shall include a QA Narrative that includes a short section describing the QA activities that will be done for the work included in Task 3.

Under this task, the Contractor shall perform other necessary communication activities related to management of the PWS. Participation in technical team calls and other discussions scheduled by EPA will also occur in conjunction with the tasks below.

Task 3: Document production for the Final Report

The Contractor shall assist with production of the Final Connectivity Report. Specific tasks shall include (but may not be limited to): production and revision of figure graphics; technical editing of chapters; formatting of the final draft to ensure that table of contents, figures and tables, figure and table lists, and reference sections all display properly; development of document design and layout to create a visually interesting report; technical editing; management of the Endnote citation database; and production of a print-ready pdf file. The Contractor shall create: (1) a formatted Word version of the Final Report; based on the template used for the Bristol Bay Assessment (2) full cover layout with bleeds that includes a spine as well as a separate front and back cover (for the web) in InDesign and pdf; and (3) a print-ready pdf report file.

Figure graphics include minor revision of existing graphics (in adobe illustrator format) and production of 4-6 new figures illustrating (1) hydrologic, chemical, and biological pathways that connect watersheds and (2) the key climate, landscape, and human factors controlling those flowpaths. These figures, drafted in powerpoint by the EPA, will include a base layer illustrating "ridge to reef" connectivity pathways and additional figures and layers conceptualizing:

- Spatial and temporal scales of connectivity,
- Hydrologic flowpaths, chemical pathways, and biological pathways,
- Effects of human alterations on connectivity.

Task 4: Response to SAB peer review and public comments

The Contractor shall assist with technical contributions to response to public comments and Science Advisory Board (SAB) comments on the Draft Report, and with preparation of the response to comment document. Responding to comments will be primarily textual, but may include some analytical (e.g., via research into supporting documentation/citations) support.

IV. DELIVERABLES AND SCHEDULE

The Contractor shall submit written deliverables as outlined by task in Exhibit 1. These deliverables must be of high quality, written in a clear, concise style, and have a logical organization and presentation. The Contractor shall submit deliverables early if they are completed ahead of schedule. The schedule shown is based on our current understanding of the project schedule. All deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g. Excel spreadsheets, Word documents, ESRI-supported geospatial files). For all listed deliverables, "days" are calendar days.

Exhibit 1
Proposed Deliverables Schedule

Task	Deliverable/Milestone	Anticipated Due Date (date or days after contract award)
Task 1 – Kickoff call	Conference call	5 days after award
Task 2 – QAPP	Final work plan and staffing plan	20 days after award
Task 3 – Document production for the Final Report	New and revised figures	30 November
	Technically edited Report chapters	30 November 2014
	Final, formatted Report	7 January 2015
Task 4 – Response to SAB peer review and public comments	Responses to SAB peer review comments	15 January 2015
	Responses to public comments	15 January 2015

V. EPA CONTACT INFORMATION

Work Assignment Manager (WAM)
Laurie Alexander, Ph.D.
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Alternate Work Assignment Manager (WAM)
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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-39

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Connectivity Report
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A. Assessment Issues & Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$49,823.00	537
Total:	$49,823.00	537

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/21/2014	$49,823.00	537
Cumulative Approved:	$49,823.00	537

Work Assignment Manager Name: Laurie Alexander (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8630 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-40

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Microbial risk
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/13/2014 To 10/31/2015

Comments:
HS 4.04.02 - 475; HS4.04.02 - 471; HS 4.04.02 - 190

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
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Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Sarah Taft (Signature) (Date)	Branch/Mail Code: Phone Number: 513-596-7037 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-40

TITLE: Microbial risk assessment methodology development and application

Specify Section & Paragraph SOW: B2. Support research, development, and application of new risk assessment methods suitable for either conducting or evaluating cumulative risk, microbial risk, mixtures risk, dose-response assessment (including extrapolation to low dose), exposure assessment, and relevant uncertainty analysis.

I. OBJECTIVES

The main objectives of this Work Assignment (WA) are to determine:

- Complete human health risk assessment summary report for *Bacillus anthracis*
- Revise reports and/or papers regarding *Bacillus anthracis* dose-response modeling and physiological characteristics of low-dose *Bacillus anthracis* exposures
- Participate in microbial risk assessment technical working groups covering *Bacillus anthracis* dosimetry and data usability strategies for field sampling data

II. BACKGROUND

The U.S. Environmental Protection Agency's (EPA's) National Homeland Security Research Center (NHSRC) was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, NHSRC is responsible for assessing potential exposures associated with the intentional or accidental release of hazardous and toxic materials including chemical, biological, and nuclear agents. NHSRC is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of NHSRC is the applications of risk assessment methodologies that can be utilized to support decision making regarding cleanup goals, treatment technology efficacies, detection limits, and waste management options during biological contamination incidents. One exposure scenario of concern is the potential for exposure to possible residual biological contamination after buildings or other areas are cleared for re-entry. Given the potentially unique hazard posed by repeated low-level exposures to *Bacillus anthracis* spores, these assessments are challenged by the identification of appropriate microbial risk assessment models and methodologies.

III. TASKS

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the Work Assignment Manager (WAM) and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Deliverables: Conference call

.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas microbial risk assessment. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

Task 3: Quality Assurance Project Plan (QAPP)

The contractor shall develop a Quality Assurance Project Plan (QAPP) to describe data quality objectives and data usage requirements for this effort. The contractor shall demonstrate in the QAPP how the organization shall plan, implement, and assess the effectiveness of its quality assurance and quality control procedures. The QAPP should incorporate a test plan to outline how the research shall be conducted and the measures taken to ensure data quality using the appropriate practices. This WA is a QA Category III Project and shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5" detailed in Appendix A. The contractor shall not perform work under Task 4-7 until the QAPP is reviewed and approved by the EPA WAM. The contractor may begin work on Tasks 1 and 2 upon receipt of this WA. The contractor is responsible for the quality of the work, data and/or measurements of any potential subcontractors. The process the contractor shall use for assessment of quality standards and measurements performed by any subcontractor shall be addressed in the QAPP.

The contractor shall provide QAPP document preparation and revision(s) as well as maintaining any additional quality assurance paperwork, including required SOPs or records of work performed. The contractor shall ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. The contractor shall ensure that this documentation is maintained in an appropriate fashion, and make this documentation available for inspection by the EPA WAM, the EPA Quality Assurance Manager or others as designated by these individuals. All supporting documentation shall be referenced and attached.

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Deliverable: QAPP

Task 4: Human Health Risk Assessment Summary for *Bacillus anthracis* Report

The contractor shall draft and complete the summary assessment report of dose-response information and human health risk assessment for *Bacillus anthracis*. The contract shall work with the EPA WAM on the appropriate outline, content, and direction of the summary report. The contractor shall provide the initial draft report for EPA WAM review and subsequent revisions with response to comment documents during the following stages: 1.) EPA technical review, quality assurance review, and security review; and 2.) EPA management review.

Deliverable: Human health risk assessment summary for Bacillus anthracis report

Performance Standard: The contractor shall provide the draft summary assessment report within 3 months after approval of work plan and QAPP.

Task 5: Independent Event Modeling and Rabbit Physiological Characterization Papers

The contractor shall revise and respond to comments per EPA technical, quality assurance, and EPA management reviews for at least two journal articles regarding independent event modeling of *Bacillus anthracis* exposures and summarizing rabbit physiological characteristics.

Deliverable: Revised journal articles

Performance Standard: The contractor shall revise journal articles within 1 month after receiving EPA comments.

Task 6: Working Group Participation

The contractor shall participate in the National Institute for Mathematical and Biological Synthesis (NIMBioS) and Microbial Data Usability working groups as deemed necessary by the WAM. Participation might include providing expertise for working group publications, collection of technical content and documents, development of methodologies needed to complete working group tasks, and facilitation of the EPA product review processes. Participation will also include travel to at least one working group meeting in Knoxville, TN, for the NIMBioS working group.

Deliverables: Working group participation

Task 7: Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WAM and the contractor to keep the project team updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations, patents, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to the WAM on request within two weeks of the request.
The contractor shall also submit combined technical and financial bi-weekly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of WAM. All documents or presentations associated with this project shall be cleared through WAM prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by WAM prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to WAM. WAM shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to WAM with responses and dispositions of comments.

All references cited in submitted reports and deliverables to WAM shall be provided to WAM either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to WAM. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by WAM, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in Adobe Acrobat format (i.e., pdf file) or paper hard copy. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

Performance Standard: The contractor shall participate in bi-weekly conference calls and meetings as needed and submit bi-weekly emails and monthly reports.

IV. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable	Performance Standard	Monitoring Method
1	Conference Call	Contractor shall participate in conference call with WAM no more than 3 days after the start of the WA	WAM shall participate in these calls to identify any issues to be addressed in the research or future reports
3	Quality Assurance Project Plan (QAPP)	Contractor shall provide the completed QAPP with the submission of the Work Plan	WAM shall document whether receipt of QAPP and Work Plan is timely and acceptable, and provide technical revisions as required
	Revised QAPP and/or Work Plan	Contractor shall revise QAPP and/or Work Plan if required and submit final QAPP and/or Work Plan no more than 15 days after receipt of revisions	WAM shall document receipt of revised QAPP and/or Work Plan, and ensure that is timely and technically acceptable
4	Human Health Risk Assessment Summary	Contractor shall provide the completed summary report within 3 months after approval of the workplan and QAPP	WAM shall document whether receipt of summary report document is timely and acceptable, and provide technical revisions as required

	Revised Human Health Risk Assessment Summary	Contractor shall revise summary report if required and submit final document no more than 30 days after receipt of revisions	WAM shall document receipt of revised summary report, and ensure that is timely and technically acceptable
5	Journal Article Revisions	Contractor shall revise journal articles within 1 month after receiving EPA comments	WAM shall document the receipt of journal article revisions, and ensure that they are timely and technically acceptable and provide technical comments as appropriate
6	Working group participation	Contractor shall participate in the working groups as deemed necessary by the WAM	WAM shall document participation in the working groups and identify any issues to be addressed
7	Bi-Weekly Conference Calls	Contractor shall participate in bi-weekly conference calls with the WAM briefly updating project progress	WAM shall participate in these calls to identify any issues to be addressed in the research or future reports
	Monthly Reports	Contractor shall prepare monthly reports as specified in the statement of work	WAM shall document receipt of monthly reports and ensure that these are timely and acceptable
	Meetings with WAM	Contractor shall have periodic meetings with the WAM as needed	WAM shall participate in these meetings and identify any issues to be addressed

VI. INTELLECTUAL PROPERTY

All methods, models, and assays developed by the contractor and/or provided to the contractor under this WA are the intellectual property of the NHSRC and Department of Homeland Security (DHS). All data collected and analyzed under this WA are the intellectual property of the NHSRC and DHS.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

The contractor shall also ensure that work under this WA does not contain any apparent or real personal or organizational conflicts of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT MANAGER (WAM) AND ALTERNATE WAM

WAM:
Sarah Taft, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7037
Cell 513/288-5460
Taft.Sarah@epa.gov

Alternate WAM:
Cynthia Yund, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7779
Yund.Cynthia@epa.gov

APPENDIX A

EPA's Quality System Website: http://www.epa.gov/quality

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html

EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approved the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

(2) an organizational chart showing the position of the QA function;

(3) delineation of the authority and responsibilities of the QA function;

(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

[X] **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

[ ] **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPPs must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

[ ] **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

[ ] **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

[ ] **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

[ ] **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

[ ] **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

[ ] **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."

[ ] **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

[X] **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

[ ] **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
NHSRC	National Homeland Security Research Center
NRMRL	National Risk Management Research Laboratory
QA ID	Quality Assurance Identification
QAPP	Quality Assurance Project Plan
QS	Quality System
TLP	Technical Lead Person
IAG	Interagency Agreement
QA	Quality Assurance
QAM	Quality Assurance Manager
QMP	Quality Management Plan
SOW	Statement of Work
CRADA	Cooperative Research & Development Agreement

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-40

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Microbial risk
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/13/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$106,583.00	695
Total:	$106,583.00	695

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 12/22/2014	$106,583.00	695
Cumulative Approved:	$106,583.00	695

Work Assignment Manager Name: Sarah Taft (Signature) (Date)	Branch/Mail Code: Phone Number: 513-596-7037 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107